

FEB 17 2012

510(k) Summary Equivital Vital Signs Physiological Monitor EQ02

Submitter: Hidalgo Ltd
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Contact: Dr Ekta Sood - Clinical Director
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Date: 2011-10-10

Name of Device:

Device Trade Name: Equivital™ Vital Signs Physiological Monitor EQ02

Device Common Name: Ambulatory Patient Monitor

Device Classification and Product Code:

EU: Class IIb

Medical Device Directive: 93/42/EEC as amended by 2007/47/EC

USA: Class II

Panel: Cardiovascular

Product Code: MHX

Regulation Number: 870.1025

Classification Name: Monitor, Physiological, Patient

(With Arrhythmia Detection Or Alarms)



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Predicate Devices

The device has been compared to the following predicate:

Hidalgo EQ01 - K061993

Additional Predicates:

GMP Wireless Medicine LifeSync™ - K030795

Dymedix Inc Re-usable Respiratory Effort Belt Sensor - K040605

Nexan Inc NX-300 - K003520

Protocol Systems Propaq Encore 200 - K012451

Respironics Actiheart® - K052489

Vivometrics Life Shirt™ Real Time - K043604

Device Description

The Equivital™ Vital Signs Physiological Monitor comprises two components:

- i) A chest belt containing skin electrodes and an expansion sensor
- ii) A battery powered electronics module which connects directly to the chest belt and which acts to record, digitise and transmit the physiological information wirelessly to a receiving display device.

The device offers continuous monitoring of two views of the user's heart electrical activity (ECG) and respiratory breathing frequency inferred from thoracic cavity movement and uses this data to derive a Heart Rate and a Breathing Effort Rate.

The sensor also provides the following information:

- ECG and Respiration physiological waveforms
- An indication of the user's activity level derived from a movement detection sensor
- Body orientation and indications for change in orientation
- Skin surface temperature
- Alternate secondary measurement of heart rate based on the detection of the user's R wave using a separate hardware processing function
- Indications and alerts if physiology exceeds predefined boundaries
- Alternate secondary skin temperature measurement using infrared thermometer

The device offers two variants for the wireless interface: a low power radio interface and a general purpose interface using Bluetooth™ technology.

The device offers two battery power options for the user, rechargeable or primary disposable cells.

The wireless data provided by the sensor may be viewed using a standalone PC based viewing application, or integrated into third party monitoring applications.

Intended Use Summary

The Equivital™ Vital Signs Physiological Monitor is an ambulatory multiparameter vital signs telemetry device intended for monitoring of adults (16 – 65 years) in hospital care facilities, the home, workplace, and alternate care settings.

The device consists of a chest belt harness and a body worn electronics module (SEM) supported by the chest belt.

The device collects and transmits ECG data and rate, respiration data and rate, skin temperature, body orientation and motion.

The monitor is indicated for use as a general patient monitor, to provide physiological information as part of an occupational welfare monitoring system, and for general research and performance measurement purposes.

Technological Characteristics

The device does not contain tissues of animal origin as referred to in EC commission directive 2003/32/EC.

Substantial equivalence has been demonstrated by technological review and comparison to the predicate Equivital EQ01 device and verified by the Design Control Process.

In addition substantial equivalence remains to the Equivital EQ01 predicate devices cited in that device's submission.

Technological Characteristics Compared:

Function	Predicate Device	Additional Predicates
ECG Heart Rate, Breathing Rate Temperature and General Physical Properties	Hidalgo Equivital EQ01 – K061993	Protocol Systems Propaq Encore 200 – K012451 Nexan Inc NX-300 – K003520
Chest Expansion Respiration	Hidalgo Equivital EQ01 – K061993	Dymedix Re-usable Respiratory Effort Belt – K040605 Nexan Inc NX-300 – K003520 Vivometrics LifeShirt Real Time – K043604
Activity/Motion Detection	Hidalgo Equivital EQ01 – K061993	Respironics Actiheart – K052489 Vivometrics LifeShirt Real Time –

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Function	Predicate Device	Additional Predicates
		K043604
Bluetooth telemetry and ECG transmission	Hidalgo Equivital EQ01 – K061993	GMP Wireless Medicine – LifeSync™ K030795
Low Power 40.68MHz PAN	Hidalgo Equivital EQ01 – K061993	Respironics Actiheart – K052489

Performance Measurement Summary

Performance measurement and review to the applicable sections of the following standards has been undertaken and successfully demonstrated as recommended by available guidance from the agency:

- EN60601-1: Medical Electrical Equipment – Part 1 General Requirements for Safety.
- IEC60601-1-2: 2001 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility.
- ISO 10993-1: Biological Evaluation of Medical Devices: Evaluation and Testing.
- ANSI/AAMI EC13: 2002 Cardiac Monitors, heart rate meters, and alarms. The device was not evaluated against the criteria for defibrillation and pacemaker immunity as it is not indicated for use in either of these cases.
- ASTM E1965 – 98 (2009) Standard Specification for Infrared Thermometers for intermittent determination of patient temperature.
- IP67: Environmental Performance Testing

The device software has been developed using a structured software lifecycle which meets the requirements of EN60601-1-4 Programmable Systems, which also applies to ongoing maintenance of the software.

Substantial Equivalence Conclusion

EQ02 has the same intended use and fundamental scientific technology as EQ01. The changes made do not raise any new questions of safety and effectiveness.

In addition the testing undertaken has demonstrated that the Equivital EQ02 device is as safe, as effective and performs as well as the legally marketed predicate Equivital EQ01 device.

To conclude substantial equivalence of the Equivital™ Vital Signs Physiological Monitor EQ02 has been demonstrated to the identified predicate Equivital™ Vital Signs Physiological Monitor EQ01.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

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Hidalgo Limited
c/o Dr. Ekta Sood
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Cambridge Cambridgeshire CB24 4UQ
GB

Re: K113054

Trade/Device Name: Equivital

Regulation Number: 21 CFR 870.1025

Regulation Name: Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms)

Regulatory Class: Class II

Product Code: MHX

Dated: January 27, 2012

Received: January 30, 2012

Dear Dr. Sood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



[Handwritten signature of Bram D. Zuckerman, M.D.]

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113054

Device Name: Equivital™ EQ02 Vital Signs Physiological Monitor

Indications For Use:

The Equivital™ Vital Signs Physiological Monitor is an ambulatory multiparameter vital signs telemetry device intended for monitoring of adults (16 - 65 years) in hospital care facilities, the home, workplace and alternate care settings.

The device consists of a chest belt harness and a body worn electronics module (SEM) supported by the chest belt.

The device collects and transmits ECG data and rate, respiration data and rate, skin temperature, body orientation and motion.

The monitor is indicated for use as a general patient monitor, to provide physiological information as part of an occupational welfare monitoring system, and for general research and performance measurement purposes.

Federal Law (US) restricts this device to sale by or on the order of a physician

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113054